

U.S.S.N. 09/776,533
FILED: February 7, 2001
RESPONSE TO RESTRICTION REQUIREMENT

requirement. The examiner is authorized to charge the requisite petition fee to our deposit order account 50-1868. This petition is being made timely, at the time the examiner decides whether or not to maintain the restriction requirement. Failure to do so creates an undue hardship on the applicants, who will have lost years of patent term based on the original restriction requirement which is radically different from the restriction requirement here.

Moreover, the parent case, based on the claims as originally restricted, has been examined, evidence submitted, and is now on appeal. Arguments have been made that results with one species are predictive of results with another species, all of which are joined by a common function: inhibition of leukocyte adhesion and function. It is well established that a genus can be linked by a common function, to achieve a common result: in this case, modulation of vascular healing, and in particular, prevention or mitigation of restenosis.

This is even truer in this case where the examiner has not only divided the generic claims into different groups based merely on the description of what different molecules can be used in the method as described in the specification, but further separated the different types of molecules (antibodies, protein ligands) based on what the molecules bind to. This is totally improper. Claims 1-4 and 11-12, as follows, are generic - the examiner is trying to impose limitations NOT PRESENT IN THE CLAIMS through the vehicle of a restriction requirement.

1. A method of inhibiting or reducing stenosis or restenosis of a blood vessel following injury to vascular tissue in a region of the blood vessel of a patient in need of treatment thereof, comprising:

administering systemically or at the site of the injury a pharmaceutically acceptable composition comprising a compound which specifically inhibits or reduces leukocyte integrin-mediated adhesion or function in an amount effective to inhibit or reduce stenosis or dependent restenosis of a blood vessel following injury to vascular tissue.

2. The method of claim 1 wherein the leukocytes are monocytes or granulocytes.

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3. The method of claim 1 wherein the injury arises from angioplasty, atherectomy, endovascular stenting, coronary artery bypass surgery, peripheral bypass surgery, or transplantation of cells, tissue or organs.

4. The method of claim 1 wherein the composition is in a form selected from the group consisting of solutions, gels, foams, suspensions, polymeric carriers, and liposomes.

11. The method of claim 1 wherein the compound is administered to a patient in need thereof prior to vascular intervention.

12. The method of claim 11 wherein the compound is administered to a the patient prior to and after vascular intervention, until healing has occurred.

The proper action in a case like this, as the examiner previously made, is to issue a restriction requirement between the method and composition claims, and an election of species requirement as recited by the twenty-four groups of the restriction requirement.

Applicants therefore elect as the species the use of Mac-1-specific antibodies.

In summary, the restriction requirement is improper because the claims to the method, claims 1-12, are linked by a common function: modulation of vascular healing by inhibition of leukocyte adhesion. The restriction requirement is further improper because to make it after the parent case has been prosecuted through appeal, and is now sitting at the Board of Appeals, based on a different restriction requirement, unfairly prejudices the applicants. The restriction requirement is still further improper because the examiner is using a restriction requirement to insert limitations into the claims which are not present.

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Consideration of all claims 1-12, on the merits, based on the elected species of Mac-1 specific antibodies is earnestly solicited.

The applicants will shortly submit data showing that the elected species is effective in primates in preventing restenosis.

Respectfully submitted,



Patrea L. Pabst
Reg. No. 31,284

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HOLLAND & KNIGHT LLP
One Atlantic Center, Suite 2000
1201 West Peachtree Street
Atlanta, Georgia 30309-3400
(404) 817-8473
(404) 817-8588 (Fax)